

**IN THE CLAIMS**

Please amend the claims as follows:

1.     **(Currently Amended)**     A sprayable composition for topical application, the composition comprising:

from about 0.0001% to about 30% w/w of at least one medicament for systemic or topical availability,

at least one non-foaming film former comprising from about 0.0001% to about 10% w/w of the composition in at least one non-aqueous vehicle;

and at least one component selected from the group consisting of:

at least one permeation enhancer;

at least one solubilizer; and

at least one plasticizer;

the composition forming a stable, non-foam, breathable film upon application to a surface.

2.     **(Currently Amended)**     The composition according to claim 1, comprising from about 0.0001 % to about 10% w/w of the at least one medicament.

3.     **(Currently Amended)**     The composition according to claim 1, comprising from about 0.0001% to about 5% w/w of the at least one medicament.

4.     **(Cancelled)**

5.     **(Cancelled)**

6.     **(Currently Amended)**     The composition according to claim 1, comprising at least one permeation enhancer in an amount of from about 0.0001 % to about 8% w/w of the composition.

AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.116

Serial Number: 10/686,517

Page 4

Filing Date: October 16, 2003

Dkt: 3355.001US2

Title: TOPICAL SPRAY COMPOSITIONS

---

7. **(Cancelled)**

8. **(Currently Amended)** The composition according to claim 1, comprising at least one solubilizer in an amount of from about 0.0001% to about 10% w/w of the composition.

9. **(Cancelled)**

10. **(Currently Amended)** The composition according to claim 1, comprising at least one plasticizer in an amount of from about 0.0001 % to about 10% w/w of the composition.

11. **(Cancelled)**

12. **(Original)** The composition according to claim 1, wherein the at least one medicament is locally or transdermally available.

13. **(Cancelled)**

14. **(Original)** The composition according to claim 1, wherein the composition comprises at least one medicament which is released from the composition immediately upon application to a biological surface.

15. **(Original)** The composition according to claim 1, wherein the composition comprises at least one medicament which is released from the composition over an extended period of time after application to a biological surface.

16. **(Cancelled)**

17. **(Original)** The composition according to claim 1, wherein the at least one medicament is selected from the group consisting of anti-emetics, anti-anginals, anti-inflammatory agents, steroids, steroid hormones, bronchodilators, drugs used to treat osteoporosis, drugs used to treat incontinence, antidepressants/anxiolytics, antimigraine agents, agents used in smoking cessation therapy, antidiarrheals, antiulcerants, anticholinergics, anticonvulsants, drugs for mood disorders/obsessive compulsive disorder, ACE inhibitors, calcium channel blockers, antihypertensives/diuretics, antiobesity drugs, hormonal peptides and analogues, drugs for benign prostatic hyperplasia/urinary retention and erectile dysfunctions, antiparkinson agents such as dopamine agonists and MAO inhibitors, drugs for sleep disorders and antidiabetic agents.

18. **(Original)** The composition according to claim 1, wherein the at least one medicament is selected from the group consisting of scopolamine, nitroglycerine, clonidine isosorbide dinitrate, propanolol hydrochloride, timolol maleate, clonazepam, verapamil, diclofenac sodium, naproxen sodium, ibuprofen, ketoprofen, indomethacin, piroxicam, ketorolac, tromethamine, nimesulide, hydrocortisone and esters thereof, dexamethasone, fluocinolone acetonide and betamethasone and salts thereof, estradiol and norethisterone or their pharmaceutically acceptable salts and combinations thereof, testosterone, progesterone, salbutamol and salts thereof, bambuterol, salmeterol xinafoate, fluticasone propionate, mometasone furoate, budesonide, beclomethasone dipropionate, sodium cromoglycate or isoprenaline sulphate, alendronic acid, pamidronic acid, etidronic acid or salts thereof, vasopressin, oxybutynin, imipramine, mitrazapine, desipramine, naratriptan, zolmitriptan, sumatriptan, nicotine, loperamide, misoprostol, hyoscymine, atropine, trihexyphenidyl, lorazepam, diazepam, tiagabine, fluoxetine, paroxetine, lisinopril, trandolapril, captorpril, amlodipine, felodipine, prazosin, amiloride, methamphetamine, sibutramine hydrochloride, nafarelin, leuprolide acetate, insulin, growth hormone and analogues thereof, doxazosin, tamsulosin, terazosin, finasteride, alprostadil, sildenafil citrate, bromocriptine, cabergoline, selegiline, melatonin, glimepiride, rosiglitazone, glyburide, glipizide and combinations thereof.

19. **(Original)** The composition according to claim 1, wherein the at least one medicament is present as a single enantiomer.

20. **(Previously Presented)** The composition according to claim 6, wherein the at least one permeation enhancer is selected from the group consisting of lipophilic solvents, surfactants, oleic acid, octyl dimethyl benzoic acid, menthol, mixed esters of capric and caprylic acid, polyhydric alcohols, dimethyl sulfoxide, dimethyl formamide, isopropyl myristate, Tween, sodium lauryl sulfate, propylene glycol, transcutol and combinations thereof.

21. **(Cancelled)**

22. **(Cancelled)**

23. **(Previously Presented)** The composition according to claim 1 wherein the at least one non-aqueous vehicle is selected from the group consisting of acetone, isopropyl alcohol, methylene chloride, methyl ethyl ketone, absolute alcohol, ethyl acetate, trichloromonofluoroethane (P11) and methylene dimethyl ether.

24. **(Cancelled)**

25. **(Currently Amended)** The composition according to claim 1, further comprising at least one propellant, wherein the at least one propellant comprises from about 10% to about 90% w/w of the composition.

26. **(Previously Presented)** The composition according to claim 25, wherein the at least one propellant is selected from the group consisting of a hydrocarbon, a hydrofluorocarbon, hydrochlorofluorocarbon, a compressed gas propane, butane, isobutane, dimethylether, dichlorodifluoromethane (P12), trichloromonofluoromethane (P11),

dichlorofluoroethane, monochlorodifluoromethane (P22), dichlorotetrafluoroethane (P114), difluoroethane (P152A), tetrafluoroethane (P134A), heptafluoropropane (P227B), nitrogen and carbon dioxide.

27-30. **(Cancelled)**

31. **(Original)** The composition according to claim 1, wherein the at least one film-former is selected from the group consisting of acrylic polymers or copolymers, polyvinyl acetate, cellulose acetate, polyvinyl alcohol, povidone, copolypovidone povidone vinyl acetate, hydroxypropyl methyl cellulose, hydroxyethyl cellulose, methyl cellulose and ethyl cellulose.

32. **(Original)** The composition according to claim 31, wherein the acrylic polymer or copolymer is selected from the group consisting of non-ionic copolymers of methyl methacrylate and butyl methacrylate, copolymers of dimethylamine ethyl methacrylate and a neutral methacrylic acid ester, ammonio methacrylate copolymer type B, ammonio methacrylate copolymer type A, methacrylic acid copolymer type A and methacrylic acid copolymer type B.

33. **(Previously Presented)** The composition according claim 8, wherein the at least one solubilizer is selected from the group consisting of copolymers of dimethylamine ethyl methacrylate and a neutral methacrylic acid ester, a surfactant, a polyhydric alcohol, vitamin E, vitamin E TPGS (tocopheryl polyethylene 1000 succinate), labrasol, propylene carbonate, sodium lauryl sulphate, Tweens, spans, propylene glycol polyethylene glycol and combinations thereof.

34. **(Cancelled)**

35. **(Previously Presented)** The composition according to claim 10, wherein the at least one plasticizer is selected from the group consisting of triethyl citrate, dimethyl

AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.116

Serial Number: 10/686,517

Filing Date: October 16, 2003

Title: TOPICAL SPRAY COMPOSITIONS

Page 8

Dkt: 3355.001US2

isosorbide, acetyltributyl citrate, castor oil, propylene glycol, polyethylene glycol, and combinations thereof.

36. **(Cancelled)**

37. **(Currently Amended)** A composition comprising:  
from about 0.0001 % to about 30% w/w of at least one medicament for topical or systemic availability,  
at least one non-foaming film-former comprising from about 0.0001 % to about 10% w/w of the composition,  
at least one solubilizer,  
at least one permeation enhancer, and  
at least one vehicle;  
said composition forming a stable, non-foam, breathable film upon application to a surface.
38. **(Currently Amended)** The composition according to claim 37, wherein the at least one medicament comprises from about 0.0001 % to about 10% w/w of the composition.
39. **(Currently Amended)** The composition according to claim 37, wherein the at least one medicament comprises from about 0.0001 % to about 5% w/w of the composition.
40. **(Currently Amended)** The composition according to claim 37, wherein the at least one solubilizer comprises from about 0.0001% to about 10% w/w of the composition, and the at least one permeation enhancer comprises from about 0.0001 % to about 8% w/w of the composition.

Claims 41-43 **(Cancelled)**

AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.116

Serial Number: 10/686,517

Filing Date: October 16, 2003

Title: TOPICAL SPRAY COMPOSITIONS

Page 9

Dkt: 3355.001US2

44. **(Original)** The composition according to claim 37, further comprising from about 0.0001 % to about 7% of at least one water soluble additive.

45. **(Original)** The composition according to claim 37, wherein the film-former is a nonionic copolymer of methyl methacrylate and butyl methacrylate and the solubilizer is a copolymer of dimethylamine ethyl methacrylate and a neutral methacrylic acid ester.

Claims 46-73 **(Cancelled)**

74. **(Previously Presented)** The sprayable composition of claim 1, further comprising dimethyl isosorbide.

75. **(Previously Presented)** The sprayable composition of claim 10, wherein the plasticizer is dimethyl isosorbide.

76. **(Previously Presented)** The sprayable composition of claim 1, wherein the composition is not an aerosol.

77. **(Previously Presented)** The sprayable composition of claim 37, wherein the composition is not an aerosol.

78. **(Currently Amended)** The sprayable composition of claim 1, comprising at least one film former comprising from about 0.0001% to 10% w/w of the composition.

79. **(Currently Amended)** The sprayable composition of claim 37, comprising at least one film former comprising from about 0.0001 % to 10% w/w of the composition.

80.     **(Currently Amended)**     The composition according to claim 37, wherein the at least one non-aqueous vehicle comprises water, at least one non-aqueous solvent, or at least one non-aqueous propellant.

81.     **(Currently Amended)**     The composition according to claim 37, wherein the at least one non-aqueous vehicle comprises from about 1 % to about 20% (w/w) of at least one humectant.

82.     **(Previously Presented)**     The composition according to claim 81, wherein the at least one humectant is selected from the group consisting of polyhydric alcohols polyvinyl pyrrolidone, propylene glycol, butylene glycol, a polyethylene glycol, glycerol and sorbitol.

83.     **(Currently Amended)**     The composition according to claim 44, wherein the at least one water soluble additive is selected from the group consisting of propylene glycol, sodium lauryl sulfate, one or more polaxomers, polyoxyl 35 castor oil, polyoxyl 40 hydrogenated castor oil, cetomacrogol, polyethylene glycol, diethylene glycol, monoethyl ether EP (transcutol), Tweens, vitamin E (TPGS), glycerol, and combinations thereof.

84.     **(New)**     A sprayable non-foaming composition for topical application, comprising:

from about 0.0001% to about 30% w/w of testosterone;  
from about 0.0001% to about 10% w/w of copovidone; and  
ethanol;

the composition forming a stable non-foam breathable film upon application to a biological surface.

85.     **(New)**     The sprayable composition of claim 84, further comprising:  
at least one component selected from the group consisting of;  
at least one permeation enhancer;

**AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.116**

Serial Number: 10/686,517

Filing Date: October 16, 2003

Title: TOPICAL SPRAY COMPOSITIONS

---

**Page 11**

Dkt: 3355.001US2

at least one solubilizer; and  
at least one plasticizer;  
the composition forming a stable, non-foam, breathable film upon application to a biological surface.

86.     (**New**)     The sprayable composition of claim 84, comprising:  
from about 0.0001 % to about 10% w/w of testosterone for systemic or topical availability;  
from about 0.0001% to about 10% w/ of copovidone; and  
ethanol;  
the composition forming a stable, non-foam, breathable film upon application to a biological surface.

87.     (**New**)     The sprayable composition of claim 84, wherein the biological surface is skin.

88.     (**New**)     The sprayable composition of claim 84, further comprising a non-aqueous propellant.

89.     (**New**)     A composition comprising:  
from about 0.0001 % to about 30% w/w of testosterone for topical or systemic availability;  
from about 0.0001 % to about 10% w/w of copovidone; and  
ethanol;  
the composition forming a stable non-foam breathable film upon application to a biological surface.

90.     (**New**)     The composition of claim 89, further comprising:  
at least one component selected from the group consisting of;

**AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.116**

Serial Number: 10/686,517

Filing Date: October 16, 2003

Title: TOPICAL SPRAY COMPOSITIONS

---

**Page 12**

Dkt: 3355.001US2

at least one permeation enhancer;

at least one solubilizer; and

at least one plasticizer;

the composition forming a stable, non-foam, breathable film upon application to a biological surface.

91.     (**New**)     The composition of claim 89, comprising:

from about 0.0001 % to about 10% w/w of testosterone for systemic or topical availability;

from about 0.0001% to about 10% w/w of copovidone of copovidone; and ethanol;

the composition forming a stable, non-foam, breathable film upon application to a biological surface.

92.     (**New**)     The composition of claim 89, wherein the biological surface is skin.

93.     (**New**)     A sprayable non-foaming composition for topical application, comprising:

from about 0.0001% to about 30% w/w of estradiol;

from about 0.0001% to about 10% w/w of copovidone; and ethanol;

the composition forming a stable non-foam breathable film upon application to a biological surface.

94.     (**New**)     The sprayable composition of claim 93, further comprising:

at least one component selected from the group consisting of;

at least one permeation enhancer;

at least one solubilizer; and

at least one plasticizer;

**AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.116**

Serial Number: 10/686,517

Filing Date: October 16, 2003

Title: TOPICAL SPRAY COMPOSITIONS

**Page 13**

Dkt: 3355.001US2

---

the composition forming a stable, non-foam, breathable film upon application to a biological surface.

95.     (**New**)     The sprayable composition of claim 93, comprising:  
from about 0.0001 % to about 10% w/w of estradiol for systemic or topical availability;  
from about 0.0001% to about 10% w/w of copovidone; and  
ethanol;  
the composition forming a stable, non-foam, breathable film upon application to a biological surface.

96.     (**New**)     The sprayable composition of claim 93, wherein the biological surface is skin.

97.     (**New**)     The sprayable composition of claim 93, further comprising a non-aqueous propellant.

98.     (**New**)     A composition comprising:  
from about 0.0001 % to about 30% w/w of estradiol for topical or systemic availability;  
from about 0.0001 % to about 10% w/w of copovidone; and  
ethanol;  
the composition forming a stable non-foam breathable film upon application to a biological surface.

99.     (**New**)     The composition of claim 98, further comprising:  
at least one component selected from the group consisting of;  
at least one permeation enhancer;  
at least one solubilizer; and  
at least one plasticizer;

**AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.116**

Serial Number: 10/686,517

Filing Date: October 16, 2003

Title: TOPICAL SPRAY COMPOSITIONS

**Page 14**

Dkt: 3355.001US2

---

the composition forming a stable, non-foam, breathable film upon application to a biological surface.

100. **(New)** The composition of claim 98, comprising:

from about 0.0001 % to about 10% w/w of estradiol for systemic or topical availability; from about 0.0001% to about 10% w/w of copovidone of copovidone; and ethanol;

the composition forming a stable, non-foam, breathable film upon application to a biological surface.

101. **(New)** The composition of claim 98, wherein the biological surface is skin.